

US EPA ARCHIVE DOCUMENT

Appendix I

High Throughput Pre-Screen (HTPS) Demonstration

[NOTE TO THE READER: The following is language taken verbatim from the request for proposal issued by EPA.]

The U.S. Environmental Protection Agency (EPA) is issuing a request for proposal for services for which the Government intends to award a firm fixed price purchase order using the Simplified Acquisition Procedures of FAR Part 13. The SIC code for this purchase order is 8734. The EPA is FACNET certified. Any contractor/vendor able to meet the enclosed requirements must demonstrate through a written proposal by the closing date of February 02, 1998. This notice is intended for competitive purposes, with no copies of the RFQ intended on being mailed.

You may E-mail the Contracting Officer at Fischer.Erich@epamail.epa.gov. Please include the following with any correspondence: Company Name, Address, phone number, business class, and e-mail address. NO PHONE CALLS WILL BE ACCEPTED. Award will be made to the firm whose offer provides the greatest value to the Government, with price, quality, and delivery performance factors considered. Award may be based on lowest overall evaluated cost. Three copies of all proposals, for the following statement of work, should be mailed to the following address (fax/e-mail copies will not be accepted): US EPA; Mail Code 3803R; ATT: Erich Fischer; 401 M Street SW; Washington, DC 20460. **HAND CARRY TO/COURIER/OVERNIGHT CARRIER ADDRESS:** Ronald Reagan Building; 1300 Pennsylvania Avenue, NW; Bid and Proposal Room; 6th Floor - Room 61107; Washington, DC 20460. The due date will be February 02, 1998, 3:00pm EST (Any proposal received after the due date will not be considered or opened.) **NO OTHER INFORMATION IS AVAILABLE AT THIS TIME.** By or before January 06, 1998, you will be able to access the EPA website at WWW.EPA.GOV/OAM/HPOD and download a copy of the RFQ along with a status bar. All questions must be addressed in writing and will be answered in writing. Questions will be due to the Contracting Officer no later than January 13, 1998 with answers being posted to the internet no later than January 20, 1998. RFQ IS AS FOLLOWS:

TITLE: HIGH THROUGHPUT PRE-SCREEN (HTPS) DEMONSTRATION

I. Background

There is concern that some chemicals can interfere with endocrine system functioning (endocrine disruptors). Endocrine disruptors have the potential to cause serious consequences for wildlife and humans, especially during early stages of development. This concern resulted in the passage of legislation (amendments to the Safe Drinking Water Act and the Food Quality Protection Act) mandating the Environmental Protection Agency (EPA) to develop and implement a screening strategy for endocrine disruptors.

- EPA has established an advisory committee comprised of industry, environmental and public health groups, Federal and state agencies, and academic experts to assist the Agency in addressing the difficult technical and policy issues involved in screening chemicals which may have the potential to disrupt the endocrine system. This committee is known as the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC).

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- EDSTAC noted there are no data related to endocrine effects for the vast majority of chemicals. To provide some minimal information on endocrine disruption potential to set priority for further screening, EDSTAC is considering recommending that EPA obtain data on a large number of chemicals using automated *in vitro* assays for detecting the ability of chemicals to interact with the estrogen and androgen receptors. These assays have been used extensively by the pharmaceutical industry to screen compounds for estrogenic, anti-estrogenic, androgenic, and anti-androgenic, and thyroid activity. EPA and EDSTAC believe that the applicability of this technology for screening commercial chemicals, pesticides and environmental contaminants should be demonstrated prior to its general use.

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- EPA is therefore soliciting proposals for this demonstration for firms experienced in this technology. If this demonstration is successful, the EPA will consider issuing a solicitation for conducting a High Throughput Pre-Screen (HTPS) for estrogenic, anti-estrogenic, androgenic, anti-androgenic, and thyroid activity for pesticides, commercial chemicals, and environmental contaminants to the laboratory that conducted the demonstration. EPA estimates that the High Throughput Pre-Screen demonstration will be conducted on 50 to 100 chemicals, whereas the HTPS program would probably examine between 5,000 and 20,000 chemicals.

II. Scope of Work - Tasks

- A. Development of Proposal... 1. The Contractor shall develop a proposal from a set of available and validated methods for an automated assay system to determine the

potential of chemical compounds to bind to estrogen alpha, estrogen beta, androgen and thyroid receptors. In addition to receptor binding, the methods should test for receptor mediated gene transcription. The assays should be run with and without metabolic activation (to detect chemicals whose metabolic products may be endocrine disruptors), be capable of identifying both agonists and antagonists, and allow for determination of relative potency (EC-50). The Contractor should provide data indicating the number of replicates that would be necessary to demonstrate that the assay is valid and reproducible for screening pesticides, commercial chemicals and environmental contaminants. **2.** The Contractor's proposal must address preparation and processing the chemicals to be assayed using accepted and validated methods. **3.** The Contractor shall specify in the proposal the assays that will be used in the HTPS by name, cell type, conditions (e.g., with/without metabolic activation etc.), and state or reference the protocol to be followed. **4.** The Contractor's proposal should address the basis for claiming that the methods for handling chemicals and assays are valid. This may include references to a formal validation program or to experience with the assay that demonstrated its validity.

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B. Demonstration of Assays... Using an automated system, the Contractor shall perform the assays described in part A on chemicals specified by EPA (ranging in number between 50 and 100). EPA would expect the contractor to order chemicals available from commercial specialty chemical suppliers. The Agency would acquire and supply others that were not available from commercial sources.

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C. Final Report... The Contractor shall furnish EPA with a report, describing the methods actually used, providing the results of each assay, and discussing any limitations or difficulties found in applying the assay to the chosen set of chemicals. Relative potency (EC-50s) should be presented in data tables in the report.

III. Work Approach

1. The Contractor shall submit a work plan in accordance with the requirements of this contract. **2.** The Contractor shall meet with EPA staff to discuss the contractor's work plan and any technical or logistical issues prior to the initiation of the demonstration program. **3.** The Contractor shall be responsible for oversight of the deliverables on this delivery order and shall be responsible for transmission of monthly reports and invoices as required by the contract.

- The contractor shall approach this task in accordance with the terms of the basic contract.
- In gathering information or performing research with parties outside the EPA, the contractor will identify him/her self as a contractor to EPA not an EPA employee
- The contractor shall provide input or recommendations based on the information gathered, however, decisions on all substantive issues will be made by EPA. THE CONTRACTOR SHALL NOT INTERPRET EPA POLICY ON BEHALF OF EPA NOR MAKE DECISIONS ON ITEMS OF POLICY, REGULATION OR STATUTE. THE CONTRACTOR SHALL NOT TAKE A STAND ON THE MERITS OF SUBSTANTIVE ITEMS UNDER DISCUSSION.

IV. Reports and Deliverables

- The Contractor shall send EPA all reports in accordance with the terms of the basic contract.
- The Contractor shall provide a work plan within the schedule provided in the basic contract and set out below.
- Copies of all reports and other written deliverables shall be sent to both the PO and DOPO listed below. If oral briefings are scheduled for EPA staff, the PO shall be notified in time to attend.
- All reports shall be provided first in draft form. Upon receipt of comment from the EPA PO and DOPO, the Contractor shall revise the report and distribute final copies as stated in Scope of Work.

Schedule: Work Plan is due 14 days from D.O. issuance. Final Report is due two weeks from receipt of comments of EPA Project Officer.

V. Award of Request for Fixed Quote

EPA will award the contract based on a combination of technical merit and cost. Some of the factors that will be considered are:

1. the degree of validation, standardization, and sensitivity of the assays;
2. the cell line's stability and ease of culturing;
3. the experience and expertise of the laboratory in conducting the assays;
4. the method of metabolic activation in the assays;
5. state of the art technology; and
6. the degree to which the assay is commercially available.

VI. Period of Performance

The period of performance for this delivery order shall be until May 1, 1998.